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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,091	02/05/2001	Dusan Pavcnik	PA-5213-CIP	2451

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EXAMINER	
BLANCO, JAVIER G	
ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/777,091	PAVCNIK ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-13,15,16 and 55-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *59* is/are allowed.

6)☒ Claim(s) *1, 2, 4, 5, 7-12, 15, 16, 55-58, and 60-67* is/are rejected.

7)☒ Claim(s) *6 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1, 7, 8, 12, 55, 60, 61, and 64 in the reply filed on March 7, 2007 is acknowledged.

2. Applicants' addition of claims 66 and 67 in the reply filed on March 7, 2007 is acknowledged.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 5, 7-9, and 58 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Duran (US 5,489,297; cited in Applicant's IDS).

Referring to Figures 110, 16A-16E, 22, and 23, Duran discloses a valve comprising:

(i) A frame (stent 110) having two or more sides (a strut/leg may have an anterior side, a posterior side, and two lateral sides), the frame formed into two or more legs (each one of the three commissure supports 146 comprises at least two legs) and comprising a bioabsorbable material (e.g., polyglycolic acid, polylactic acid, polyethylenes, polyhydroxybutyrate, collagen, soluble sugars, etc; see column 11, lines 45-67);

(ii) A covering (membrane 112) attached to at least two sides (e.g., wrapped around the strut/leg) of a first leg, a second leg, and a third leg *to form* (emphasis added to functional language) the body of a first leaflet, a second leaflet, and a third leaflet, the covering comprising a material with remodeling properties (e.g., pericardium, pleura, peritoneum, fascia lata, or other biological membrane sources; see column 12);

(iii) Each leaflet having an inner body edge (cooperating with the inner body edge of another leaflet to form the opening of the valve prosthesis) and an outer body edge (attached to the support frame); and

(iv) Wherein each of the inner body edges comprises a flexible free edge (e.g., free edges 117) that defines a portion of the valve orifice.

The device of Duran '297 is flexible, bendable, and capable of moving from a radially compressed configuration to a radially expanded configuration if one skilled in the art so desires. During implantation/manipulation, the device will be radially compressed (i.e., for insertion, as it is well known in the art) and subsequently radially expanded (i.e., to conform and/or press against the vessel wall). As clearly shown in Figure 10 (see column 6, lines 7-10), the support frame is "adapted to" assume a generally flat plane. The final product will have a serpentine configuration. Regarding claim 4, the "overhang portion" is broadly interpreted as the portion (see Figure 16E) in between the outer edges, and extending beyond (e.g., away) the support frame. Regarding claims 7 and 8, the term "integral" is broadly interpreted as "unitary", or forming an unit.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does."

Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

5. Claims 60 and 63-67 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Andersen et al. (US 5,411,552; cited in Applicants' IDS).

As seen in Figures 1-3, Andersen et al. disclose an implantable valve comprising a self-expandable or balloon-expandable frame (stent 1; see column 2, lines 45-57; column 7, lines 21-23) having a plurality of bends (Figures 1 and 2: apices) and interconnected side elements (struts in between apices), and a plurality of leaflets (valve 6: made from either a biological material or a synthetic material) with inner edges defining an opening to permit fluid flow in a first direction and restricting fluid flow in a second opposite direction, and outer edges attached along one side element and adapted to sealingly engage the wall of the bodily passage (see entire document). As disclosed in column 7 at lines 1-4, the valve prosthesis construction can be modified, depending on the intended purpose. As disclosed in column 7 at lines 13-16, the valve prosthesis can be a bi-leaflet valve prosthesis. The "outer edge" can be an edge attached to a strut and/or apex/bend of the stent (see folded wires 2 and 3, shown in Figure 2). The "inner edge" can be an edge attached to the commissures 4 (it should be noted that each commissure is shaped as a bend) and/or sealing edges (i.e., the ones defining the valve opening) of the two leaflets.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

6. With regards to the 102(e) rejection based on Andersen et al. (US 5,411,552; cited in Applicants' IDS), Applicants' arguments filed March 7, 2007 have been fully considered but they are not persuasive.

a. Regarding claim 60, the Applicants argue that Andersen et al. do not disclose the functional limitation "such that the plurality of outer edges engage the walls of the bodily passage and collectively form a seal thereagainst". The Examiner respectfully disagrees. From Figures 2, 7, and 12, it is inherent the outer edges (i.e., edges attached to struts and/or apices/bends of the stent) necessarily engage the wall of the vessel to create said seal in order to avoid malfunctioning (i.e., leaking) of the valve prosthesis. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an intended operation

are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

7. Claims 1, 2, 4, 5, 7-9, and 58 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Moll et al. (US 6,287,334 B1; cited in Applicants' IDS).

As seen in Figures 1-6, Moll et al. disclose an implantable valve comprising a support frame (support frame 10) providing a plurality of side elements defining a path extending at least partially longitudinally along the wall and at least partially circumferentially around the wall (see Figures 1 and 2), and a plurality of leaflets (valve elements or blood flow stoppage elements 6) which inner edges define an opening to permit fluid flow in a first direction (see Figure 5) and engage each other to restrict fluid flow in a second opposite direction (see Figure 6). The outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements (see Figure 1; see entire document). Regarding claim 4, the "overhang portion" is broadly interpreted as the portion (see portion 14) in between the outer edges, and extending beyond (e.g., away) the support frame. Regarding claims 7 and 8, the term "integral" is broadly interpreted as "unitary", or forming an unit. As seen in Figure 2, the frame can initially assume a generally flat configuration.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an

intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

8. With regards to the 102(e) rejection based on Moll et al. (US 6,287,334 B1; cited in Applicants' IDS), Applicants' arguments filed March 7, 2007 have been fully considered but they are not persuasive.

a. Regarding claim 1, the Applicants argue that Moll et al. do not disclose the functional limitation "each leaflet extending along said bodily passage away from the inner edges thereof in said second direction to form a curved structure for trapping fluid against the inner wall of the bodily passage". The Examiner respectfully disagrees. In the "second direction" (i.e., inner edges engage each other), the outer edges (Figure 1: edges attached to support frame 10 resiliently and sealingly engage the wall of the bodily passage along the path, and each leaflet form a curved structure for trapping fluid against the inner wall of the bodily passage. Blood will be indirectly trapped between the curved surface of the leaflet and the wall of the vessel. Further, blood will also be trapped between the curved surfaces of the leaflets (at proximal end 2) and the wall of the vessel. Regarding claim 5, it should be noted that Moll et al.'s claim 1 clearly states the leaflets as attached to support frame 10. Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Expressions relating the apparatus to contents thereof during an

intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

b. Regarding claim 4, the "overhang portion" is broadly interpreted as the portion (see portion 14) in between the outer edges, and extending beyond (e.g., away) the support frame.

c. Regarding claims 7 and 8, the term "integral" is broadly interpreted as "unitary", or forming an unit.

d. Regarding claim 58, support frame 10 is "adapted to" assume a generally flat plane (see Figure 2).

9. Claims 1, 2, 4, 5, 7-9, 12, 60, 61, and 63-67 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by DiMatteo et al. (US 6,440,164 B1).

Referring to Figures 1-4, 14-16, and 25-28, DiMatteo et al. disclose an expandable implantable vascular valve (e.g., bi-leaflet valve prosthesis) comprising: (i) a support frame (trellis 24 includes scaffold 30 and leaf frames 62); (ii) one or more leaflets (e.g., valve leaf cover 80; additionally, there is a first liner 82 comprising a webbing 84) comprised of a biomaterial (see list of materials disclosed in columns 10 and 11; including biological material such as pericardial tissue, or synthetic material such as polymers) attached to the support frame; and (iii) wherein the biomaterial is wrapped around the support frame, thereby attaching the one or more leaflets to the support frame (see entire document). First liner 82 could comprise at least one flap 86, or extent 80a of liner 82, that folds over the support frame and is subsequently laminated to itself, and including the entire extent of trellis 24 as shown in Figures 1 and 3 (see column 11, lines

15-20; column 12, lines 48-55). The "overhang portion" or "skirt portion" is broadly interpreted as the portion that will "overhang" before attaching/laminating to itself. Another example of an outer edge is shown in Figures 1 and 3, wherein the line denoted by character 22 shows a portion of said leaflets in contact with the vessel wall. First liner 82 could be laminated with second liner 88, therefore encasing all of trellis 24 or just scaffold 30 (see column 11, lines 21-27 and lines 32-35). The inner edges of the plurality of leaflets cooperate to define an opening therebetween (see Figures).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 55-57, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US 5,411,552; cited in Applicants' IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS).

Andersen et al. disclose the invention as claimed (see 102(e) rejection above) except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. Andersen et al. disclose in column 7, lines 1-4, that the valve prosthesis construction can be modified, depending on the intended purpose. Further, Andersen et al. disclose in column 7, lines 12-16, that the leaflets of the valve prosthesis may use biological material, or a synthetic material. The subject matter of valve prosthesis using small intestinal submucosa as the leaflet material is already known in the art. For

example, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Andersen et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

Response to Arguments

12. With regards to the 103(a) rejection based on Andersen et al. (US 5,411,552; cited in Applicants' IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS), Applicants' arguments filed March 7, 2007 have been fully considered but they are not persuasive.

a. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971).

b. In response to Applicants' piecemeal analysis of the references, it has been held that one cannot show nonobviousness by attacking references individually where, as here, the rejections are based on combinations of references. *In re Keller*, 208 USPQ 871 (CCPA 1981).

c. The advantages of using small intestinal submucosa are clearly disclosed in the 103(a) rejection.

13. Claims 10, 11, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1; cited in Applicants' IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS).

Moll et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, this is already known in the art. For example, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Moll et al., in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

Response to Arguments

14. With regards to the 103(a) rejection based on Moll et al. (US 6,287,334 B1; cited in Applicants' IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS), Applicants' arguments filed March 7, 2007 have been fully considered but they are not persuasive.

a. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. *In re Nomiya*, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1971).

b. In response to Applicants' piecemeal analysis of the references, it has been held that one cannot show nonobviousness by attacking references individually where, as here, the rejections are based on combinations of references. *In re Keller*, 208 USPQ 871 (CCPA 1981).

c. The advantages of using small intestinal submucosa are clearly disclosed in the 103(a) rejection.

15. Claims 10, 11, and 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duran (US 5,489,297; cited in Applicant's IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS) or Peredo (US 6,254,636).

Duran discloses the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, this is already known in the art.

For example, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Duran, in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

For example, Peredo discloses a valve comprising leaflets made from small intestine submucosa (SIS), fascia lata, pericardium, dura mater, or other membranous tissue (see entire document, particularly column 3). Peredo '636 is evidence that small intestine submucosa (SIS), fascia lata, pericardium, dura mater, or other membranous tissue are functionally equivalent, compatible, and interchangeable when preparing/forming a valve for insertion in a blood vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using small intestine submucosa (SIS), fascia lata, pericardium, dura mater, or other membranous tissue, as taught by Peredo, with the valve of Duran '297, since such biological membranes are functionally equivalent, compatible, and interchangeable when preparing/forming a valve for insertion in a blood vessel.

16. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. (US 6,287,334 B1; cited in Applicants' IDS) in view of Bessler et al. (US 5,855,601 A; cited in Applicant's IDS).

Moll et al. disclose the invention as claimed except for disclosing the use of barbs to anchor the implantable valve to the wall of the bodily passage. However, the use of barbs/hooks to anchor stents to bodily passages is well known in the art. For example, Bessler et al. teach the use of a plurality of barbs 64 for holding a valve in place once it has been appropriately positioned (see Figures 6 and 7; see column 5, lines 12-14; column 5, line 67 to column 6, line 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a plurality of barbs, as taught by Bessler et al., with the valve of Moll et al., in order to hold the valve in place once it has been appropriately positioned.

17. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duran (US 5,489,297; cited in Applicant's IDS) in view of Bessler et al. (US 5,855,601 A; cited in Applicant's IDS).

Duran discloses the invention as claimed except for disclosing the use of barbs to anchor the implantable valve to the wall of the bodily passage. However, the use of barbs/hooks to anchor stents to bodily passages is well known in the art. For example, Bessler et al. teach the use of a plurality of barbs 64 for holding a valve in place once it has been appropriately positioned (see Figures 6 and 7; see column 5, lines 12-14; column 5, line 67 to column 6, line 2). It would have been obvious to one of ordinary

skill in the art at the time the invention was made to have combined the teaching of using a plurality of barbs, as taught by Bessler et al., with the valve of Duran, in order to hold the valve in place once it has been appropriately positioned.

Allowable Subject Matter

18. Claim 59 is allowed.

19. Claims 6 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

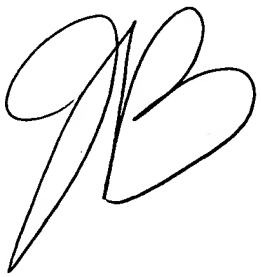
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

May 10, 2007



David H. Willse
Primary Examiner